IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): Rosen	
Application No.: 09/937,192	
Filed: 9/21/2001	Group Art Unit: 1624
Title: Methods and Compositions for Degradation and for Inhibition of HER-Family Tyrosine Kinases	Examiner: Bruck Kifle
Attorney Docket No.: MSK.P-038	

REPLY BRIEF FOR APPELLANT

This Reply Brief is filed in support of Applicants' Appeal from the rejection mailed July 11, 2005, and in response to the Examiner's Answer mailed December 12, 2005.

In the Examiner's Answer (Page 1), the Examiner states that "no evidence is relied upon by the examiner in the rejection of the claims under appeal." However, on page 5 of the Examiner's Answer he refers to a paper of Sreedhar et al. This paper is not of record in this case, and this part of the Examiner's Answer should be stricken.

It is noted with some frustration that the Examiner's Answer is essentially a reprint of prior actions, even to the point of identifying a "new ground for rejection" on Page 7. This same "new grounds for rejection" appeared in the Official Action mailed July 11, 2005, and was therefore addressed in the original appeal brief. More significantly, the Examiner has provided little or no meaningful response to the arguments made in the Appeal Brief, and has maintained the same generalized positions as before.

The Examiner's Answer states that "claims 3, 4, 6 and 9-11 are not rejected for lack of enablement." (page 9) Since these claims were rejected in the final Office Action, it is understood by

Applicants that this rejection is not maintained. Accordingly, the arguments in sections I A-C (Pages 3-5) of the Appeal brief would appear to be moot.

With respect to claim 12, the Examiner states that claim 12 is drawn to destruction of cells that include "healthy cells" and that there is no benefit in destroying healthy cells. Applicants assume this argument is made with respect to the enablement rejection, although the Examiner's Answer does not say so. It is pointed out, however, that the enablement requirement is one applied to the specification, not the claims, and if it is so apparent that there is no reason to destroy healthy cells that the Examiner can make the statement without evidentiary support, then this is the type of excluding limitation that does not need to be in a claim. *See, In re Dinh-Nguyen*, 181 USPQ 46, 48 (CCPA 1974) (It is not the function of the claims to exclude possible inoperative embodiments); *In re Kamal*, 158 USPQ 320 (CCPA 1968) (Possibility of inclusion of inoperative substances does not prevent allowance of broad claims); *In re Anderson*, 176 USPQ 331 (CCPA 1973) (claim need not be limited to operative embodiments in skilled pharmaceutical art).

On Page 10 of the Examiner's Answer, the statement is made that "Table 1 on Page 6 of the specification shows that all compounds tested are worse or considerable (sic) worse than geldanamycin." This is not relevant, since a compound need not be better to be patentable. In this case, however, the importance showing in of the data is not merely the absolute activity, but the selectivity as between the desired activity against Her2 and the undesired side effect activity against Raf-kinase. The examiner also states on Page 10 that "geldanamycin itself does not work and has not been shown to be effective against cancer and is no longer being investigated." This allegation of fact is made without evidentiary support and should be stricken from the record.[1]

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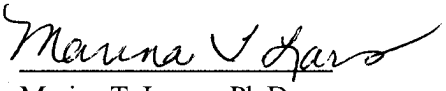
[1] Applicants further note that geldanamycin is available for sale in cancer research through the web site www.geldanamycin.com. Incidentally, as shown on the attached copy of this web page, geldanamycin is identified as an "ansamycin antibiotic" a term that the Examiner continues to assert is not understood by persons skilled in the art.

With respect to claims 14 and 21-23, the Examiner's Answer states that these claims "are limited to a cancer which is a HER-positive cancer. The scope of cancer here is not objected to." Applicants understand this to be a withdrawal of the rejection for lack of enablement on this ground. The same is true for claim 30. Based on this understand, it would appear that the arguments in Section I G and H are moot because this rejection of these claims is not maintained.

On page 11 of the Examiner's Answer, the statement is made that "if the compound cannot be crystallized one cannot observe binding." The relevance of this statement is not understood, since what was crystallized in the art was the hsp90 protein, with geldanamycin bound in the binding pocket. Whether or not geldanamycin per se, or any other hsp90-binding compound can be crystallized is not relevant.

Applicants again submit that the rejections of the present claims under 35 USC § 112, first and second paragraphs, are in error and should be reversed.

Respectfully submitted,



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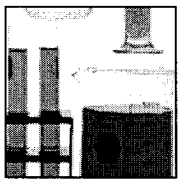

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*(Data obtained from The Angiogenesis Foundation, www.angio.org. Geldanamycin.com has no official affiliation with this foundation)

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